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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,663	07/02/2001	Antonio A. Garcia	A32011-A-PCT	2220
21003	7590	10/16/2003	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			TRAN, MY CHAU T	
		ART UNIT		PAPER NUMBER
		1639		
DATE MAILED: 10/16/2003				13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,663	GARCIA ET AL.	
	Examiner	Art Unit	
	My-Chau T. Tran	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 August 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 10-23 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

1. Claims 10-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

2. This application contains claims 10-23 that is drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Maintained Rejections

3. Claims 1-9 are treated on the merit in this Office Action.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (*Biotechnol. Prog.*, 1995, 11(4):465-467).

The instant claim 1 recites a “product” comprise of silver ions immobilized on a support. Kim et al. disclose a device that comprises a support in which Ag(I) ions are immobilized (Abstract; pg. 465, right col., lines 3-7; pg. 466, left col., lines 42-45). The amino acids formed a

complex with the silver ions (pg. 466, left col., lines 6-16). Therefore, the device of Kim et al. anticipates the presently claimed invention.

Response to Arguments

6. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Kim et al. (*Biotechnol. Prog.*, 1995, 11(4):465-467) for claim 1 was considered but they are not persuasive for the following reason.
7. In response to applicant's arguments, the recitation of "a bioassay plate" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Additionally, the presently claimed invention is structurally comprised of silver ion immobilized on a support. The device of Kim et al. is structurally comprised of silver ion immobilized on a support (pg. 465, right col., lines 3-7). Therefore the device of Kim et al. anticipates the presently claimed invention.
8. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Siiman et al. (US Patent 5,552,086).

The instant claim 1 recites a "product" comprise of silver ions immobilized on a support. The support comprise of polystyrene (claim 2).

Siiman et al. disclose a device that comprises a metal coated polymer support that is in a bioassay (col. 1, lines 32-36; col. 2, lines 50-61). The polymer includes polystyrene (col. 7, lines 35-38). The metal includes silver salt (col. 7, lines 49-57). The metal coating on the support would provide an advantage of enhancing light scattering with excitation in the visible light region (col. 2, lines 58-60). Therefore, the device of Siiman et al. anticipates the presently claimed invention.

Response to Arguments

9. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Siiman et al. (US Patent 5,552,086) for claims 1-2 was considered but they are not persuasive for the following reasons.

Applicant contends that Siiman et al. does not anticipate the presently claimed invention because the surface of the Siiman et al. device comprise of “[a]minodextran, and not silver metal or silver oxide”.

Applicant's arguments are not convincing since the surface of the Siiman et al. device is comprise of metal such as silver ions (col. 5, lines 25-28) (e.g. the “top” layer of the support is silver ion). Therefore the device of Siiman et al. anticipates the presently claimed invention.

10. Claims 5-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim et al. (*Biotechnol. Prog.*, 1995, 11(4):465-467).

The instant claims 5-9 recites a “product” comprise of silver ions immobilized on a support.

Kim et al. disclose a device that comprises a support in which Ag(I) ions are immobilized (Abstract; pg. 465, right col., lines 3-7; pg. 466, left col., lines 42-45). The amino acids formed a complex with the silver ions (pg. 466, left col., lines 6-16).

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the method of making the product of immobilized silver ions on a support. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific method of making the product of immobilizing silver ions on a support of the instant versus the reference method of making the product of immobilizing silver ions on a support. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed product of immobilizing silver ions on a support is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

The instant claims (claims 5-9) are written as product-by-process claims. "Eventhough the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claims is same or obvious from the product of the prior art, the claim is unpatentable eventhough the prior art product was made by a different process." *In re Thorpe*, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). (see MPEP 2113).

Response to Arguments

11. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Kim et al. (*Biotechnol. Prog.*, 1995, 11(4):465-467) for claims 5-9 was considered but they are not persuasive for the following reason.

12. In response to applicant's arguments, the recitation of "a bioassay plate" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Additionally, the presently claimed invention is structurally comprised of silver ion immobilized on a support. The device of Kim et al. is structurally comprised of silver ion immobilized on a support (Abstract; pg. 465, right col., lines 3-7; pg. 466, left col., lines 42-45). Therefore the device of Kim et al. anticipates the presently claimed invention.

13. Claims 5-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Siiman et al. (US Patent 5,552,086).

The instant claims 5-9 recite a "product" comprise of silver ions immobilized on a support.

Siiman et al. disclose a device that comprises a metal coated polymer support that is in a bioassay (col. 1, lines 32-36; col. 2, lines 50-61). The polymer includes polystyrene (col. 7, lines

35-38). The metal includes silver salt (col. 7, lines 49-57). The metal coating on the support would provide an advantage of enhancing light scattering with excitation in the visible light region (col. 2, lines 58-60).

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the method of making the product of immobilized silver ions on a support. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific method of making the product of immobilizing silver ions on a support of the instant versus the reference method of making the product of immobilizing silver ions on a support. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed product of immobilizing silver ions on a support is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

The instant claims (claims 5-9) are written as product-by-process claims. "Eventhough the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claims is same or obvious from the product of the prior art, the claim is unpatentable eventhough the prior art product was made by a different process." *In re Thorpe*, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). (see MPEP 2113).

Response to Arguments

14. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Siiman et al. (US Patent 5,552,086) for claims 5-9 was considered but they are not persuasive for the following reasons.

Applicant contends that Siiman et al. does not anticipate the presently claimed invention because the surface of the Siiman et al. device comprise of “[a]minodextran, and not silver metal or silver oxide”.

Applicant's arguments are not convincing since the surface of the Siiman et al. device is comprise of metal such as silver ions (col. 5, lines 25-28) (e.g. the “top” layer of the support is silver ion). Therefore the device of Siiman et al. anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

15. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (*Biotechnol. Prog.*, 1995, 11(4):465-467) in view of Longiaru et al. (US Patent 5,232,829).

The instant claim 1 recites a “product” comprise of silver ions immobilized on a support. The support comprise of a 96-well polystyrene plate (claim 2-4).

Kim et al. disclose a device that comprises a support in which Ag(I) ions are immobilized (Abstract; pg. 465, right col., lines 3-7; pg. 466, left col., lines 42-45). The amino acids formed a complex with the silver ions (pg. 466, left col., lines 6-16).

The device of Kim et al. does not expressly disclose that the support is in a plate format that is 96 wells.

Longiaru et al. disclose an immunoassay that comprise of a polystyrene solid support that has enhanced protein binding capacity (col. 3, lines 13-17; col. 6, lines 3-5). The polystyrene solid support is a microtitre plate with 96 wells (col. 7, lines 38-45). The plate capture format would provide the advantages of a quicker assay time and a less labor intensive assay format (col. 3, lines 34-38).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a support in a plate format that is 96 wells as taught by Longiaru et al. in the device of Kim et al. One of ordinary skill in the art would have been motivated to include a support in a plate format in the device of Kim et al. for the advantage of a quicker assay time and a less labor intensive assay format (Longiaru: col. 3, lines 34-38). Since both Kim et al. and Longiaru et al. disclose the support is use in a bioassay (Kim: pg. 466, left col., lines 6-16; Longiaru: col. 6, lines 3-5).

Response to Arguments

16. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Kim et al. (*Biotechnol. Prog.*, 1995, 11(4):465-467) in view of Longiaru et al.

(US Patent 5,232,829) for claims 1-4 was considered but they are not persuasive for the following reasons.

17. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case one of ordinary skill in the art would have expectation for success to combine the teaching of Kim et al. and Longiaru et al. because both Kim et al. and Longiaru et al. disclose a polymeric support (Kim: pg. 465, lines 3-4; Longiaru: col. 3, lines 12-16) (e.g. analogous art). Additionally, the presently claimed invention is structurally comprised of silver ion immobilized on a support. The device of Kim et al. is structurally comprised of silver ion immobilized on a support (pg. 465, right col., lines 3-7). Therefore combination of Kim et al. and Longiaru et al. is obvious over the presently claimed invention.

18. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In this case the presently claimed invention recites a support wherein silver ion is immobilized (claim 1). The support comprises a polymeric multiwell plate (claims 2-4). The combination of Kim et al. and Longiaru et al. is obvious over the presently claimed invention because both Kim et al. and Longiaru et al. disclose a polymeric support (e.g. analogous art). Kim et al. disclose a polymeric support wherein silver ion is immobilized (pg. 465, lines 3-4). Longiaru et al. disclose a polymeric support in a plate format (Longiaru: col. 3, lines 12-16).

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Therefore one of ordinary skill in the art would have expectation for success to combine the teaching of Kim et al. and Longiaru et al. because a plate format would provide the advantages of a quicker assay time and a less labor intensive assay format (Longiaru: col. 3, lines 34-38).

19. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siiman et al. (US Patent 5,552,086) in view of Longiaru et al. (US Patent 5,232,829).

The instant claim 1 recites a “product” comprise of silver ions immobilized on a support. The support comprise of a 96-well polystyrene plate (claim 2-4).

Siiman et al. disclose a device that comprises a metal coated polymer support that is in a bioassay (col. 1, lines 32-36; col. 2, lines 50-61). The polymer includes polystyrene (col. 7, lines 35-38). The metal includes silver salt (col. 7, lines 49-57). The metal coating on the support would provide an advantage of enhancing light scattering with excitation in the visible light region (col. 2, lines 58-60).

The device of Siiman et al. does not expressly disclose that the support is in a plate format that is 96 wells.

Longiaru et al. disclose an immunoassay that comprise of a polystyrene solid support that has enhanced protein binding capacity (col. 3, lines 13-17; col. 6, lines 3-5). The polystyrene solid support is a microtitre plate with 96 wells (col. 7, lines 38-45). The plate capture format would provide the advantages of a quicker assay time and a less labor intensive assay format (col. 3, lines 34-38).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a support in a plate format that is 96 wells as taught by Longiaru

et al. in the device of Kim et al. One of ordinary skill in the art would have been motivated to include a support in a plate format in the device of Kim et al. for the advantage of a quicker assay time and a less labor intensive assay format (Longiaru: col. 3, lines 34-38). Since both Kim et al. and Longiaru et al. disclose a polymer support is use in a bioassay (Siiman: col., lines 6-16; Longiaru: col. 6, lines 3-5).

Response to Arguments

20. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Siiman et al. (US Patent 5,552,086) in view of Longiaru et al. (US Patent 5,232,829) for claims 1-4 was considered but they are not persuasive for the following reasons.
21. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case one of ordinary skill in the art would have expectation for success to combine the teaching of Siiman et al. and Longiaru et al. because both Siiman et al. and Longiaru et al. disclose a polymeric support (Siiman: col. 5, lines 25-28; Longiaru: col. 3, lines 12-16) (e.g. analogous art). Additionally, the presently claimed invention is structurally comprised of silver ion immobilized on a support. The device of Siiman et al. is structurally comprised of silver ion immobilized on a support (col. 5, lines 25-28). Therefore combination of Siiman et al. and Longiaru et al. is obvious over the presently claimed invention.

22. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In this case the presently claimed invention recites a support wherein silver ion is immobilized (claim 1). The support comprises a polymeric multiwell plate (claims 2-4). The combination of Siiman et al. and Longiaru et al. is obvious over the presently claimed invention because both Siiman et al. and Longiaru et al. disclose a polymeric support (e.g. analogous art). Siiman et al. disclose a polymeric support wherein silver ion is immobilized (col. 5, lines 25-28). Longiaru et al. disclose a polymeric support in a plate format (Longiaru: col. 3, lines 12-16). Therefore one of ordinary skill in the art would have expectation for success to combine the teaching of Kim et al. and Longiaru et al. because a plate format would provide the advantages of a quicker assay time and a less labor intensive assay format (Longiaru: col. 3, lines 34-38).

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on Increased Flex Schedule and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
October 9, 2003



PADMASHRI PONNALURI
PRIMARY EXAMINER